

SD Board of Pharmacy Meeting Minutes
Friday, December 8 2017; 8:00 a.m. CST
South Dakota Board of Nursing Conference Room
4305 S. Louise Ave., Suite 201, Sioux Falls, South Dakota 57106

Board Members Present: President Diane Dady, Tom Nelson, Lenny Petrik, Lisa Rave, and Dan Somsen

Board Staff Present: Executive Director Kari Shanard-Koenders; PDMP Director Melissa DeNoon, Inspectors Gary Karel, Paula Stotz, Carol Smith; Secretary Beth Windschitl.

Attendees Present: Justin Manning, Brenda Jensen, Sue Schaefer, Amanda Bacon, Scott Setzepfandt, Cheri Kraemer, Jessica Harris, Amanda McNelly, Joel Kurzman, Bill Ladwig, and Michael Burns

A. Call to Order and Introductions

The meeting was called to order by President Dady at 8:03 AM CST. Diane read the Board of Pharmacy mission statement, followed by introductions of Board Members, Board Staff and audience attendees. Roll call was taken; a quorum was present.

B. Consent Agenda

Executive Director Shanard-Koenders briefly reviewed the components of the consent agenda noting that any item could be removed from the consent agenda for discussion. Motion to approve consent agenda was made by Board Member Lisa Rave and seconded by Board Member Dan Somsen. Motion carried; Diane Dady-aye, Tom Nelson-aye, Lenny Petrik-aye, Lisa Rave-aye, and Dan Somsen-aye.

C. Staff Reports

1. Recognition / Staff Report

- I. Congratulations to Cheri Kraemer the first recipient of ACHC/PCAB Distinction in Hazardous Compounding
- II. Carol Smith completed the Critical Point Certificate in Sterile Compounding for Inspectors (CISCI)
- III. Secretary Jessica Neal has rescinded her resignation and will continue working for the Board of Pharmacy
- IV. Inspector Gary Karel will retire January 8, 2018. He has been an exemplary inspector sharing his vast knowledge and expertise with staff, peers, and industry personnel for over six years. He will be greatly missed. The position has been posted seeking an individual with both hospital and retail experience.

2. Inspector Reports

a. Gary Karel

Gary noted the following items in various pharmacies:

- PIC with professional license expired, a misdemeanor in the State of South Dakota; Executive Director sent a letter to pharmacist.
- Multiple places assessing USP 800 Guidelines and working on becoming compliant.
- Still have PIC's that have not taken any steps to inform staff about NIOSH 2016 document.
- Hood tested in a location and report stated "corrective action required". After discussion with PIC, a new hood was ordered.
- Documentation of cleaning records incomplete.
- Found SDV of medication that was punctured, not dated still in refrigerator.
- High Risk Policy should be updated annually

- Found bulk vial of antibiotic that was reconstituted and frozen in refrigerator. Temperature of refrigerator was 29 degrees.
- Multiple outdated antibiotics in refrigerator made in Accuflow devices and other outdates in other facilities.
- Multiple dose vials opened but not dated with 28-day dating.
- Hospital forgot to count all controlled substances in the entire facility. They only counted controlled substances in the Pharmacy Department.
- Acute Care facility sign agreement to review pharmacy orders after hours.
- IV Room that was built with windows in Hazardous Room, Anteroom and Non-Hazardous Room got contractor to fix (enclose) windows.
- Hospital pharmacy working on getting ceiling tiles caulked.

b. Carol Smith

Carol noted the following items during inspections:

- Attended four days at Critical Point; completed 33 modules of critical _____ and nine math modules.
- Is monitoring Tramadol when inspecting; seeing miscounts, however, one facility dispensed 38,000 tablets and were only 10 short after audit.
- Filling Suboxone – not being caught at fill and review point.
- Found a facility using refrigerator for medication and food storage.

c. Paula Stotz

Paula noted the following items:

- Controlled substance audits usually very close to exactly right on, several instances where the on hand amount is long – possibly due to nursing home billing cycles.
- Some pharmacies have implemented USP 800 already, several pharmacies are waiting for their corporate entity to come up with the policies and procedures. PICs can begin developing a list of drugs handled in their particular pharmacy, and identifying hazardous drugs to begin informing pharmacy staff of special handling requirements.
- One LTC pharmacy was not getting prescriptions, (drug, quantity, sig and any refills) but rather getting prescriptions from the LTC facility – no quantity, or refill information.
- Critical Access hospital installed new isolator and had the isolator certified but did not perform the required Gloved Fingertip Sample (GFS) or Media fills prior to using the isolator.
- A physician was using the NADEAN (Narcotics Addiction DEA Number) waiver and not intending to become a Narcotic treating provider.
- Discussed with PICs, Controlled substance prescriptions that are received via fax and appear with VOID or Invalid Rx – are not valid prescriptions, the pharmacist needs to call and verify the prescription as a telephone order, or are they to obtain the original prescription from the patient, was the prescription shredded or placed in the patient's medical record, document who they spoke to along with the date and their initials.

3. PDMP Report

Director Melissa DeNoon reported the following PDMP updates:

- Reviewed PDMP prescriber mandate registration statistics – enrollment levels are high (95% of required prescribers have access to PMP AWARxE) and focus will now shift from registration to utilization and pharmacy submission compliance.
- AWARxE has new reporting capabilities with the introduction of Tableau; platform offers expanded analytics providing prescriber and therapeutic drug class specific drilldown reporting opportunities.

- Format of AWAxE platform changed on November 12, 2017.
- Sanford integration is on hold. Integration funding, from the 2016 Harold Rogers Grant, maybe reallocated to assist with Regional Health's EHR/ SD PDMP Integration.
- The Board sponsored MedDrop Drug Take-Back Program is underway with receptacles in two locations in the State, upcoming installation sites include Webster, Pierre, Martin, Sioux Falls, and DeSmet; and additional sites are being identified. Program goal was to place one receptacle in each county; however, some counties' dynamics made the objective unachievable.
- Current grant funding covers initial implementation costs for 15 sites (one receptacle and two collection bundles).
- The Harold Rogers 2016 Grant funding ends September 30, 2018. Identifying a dedicated, sustainable funding source for the Prescription Drug Monitoring Program is a Board priority. One way to increase funding is to raise licensing fees. Some States use controlled substance (CS) registrations fees to fund PDMP. In these States, CS registration is completed by the State's Board of Pharmacy.
- Reviewed upcoming PDMP related calendar events.

A. Complaints, Investigations, Disciplinary Actions, Loss/Theft Report

The following were reported by Gary Karel, Carol Smith, and Paula Stotz. Discussion followed.

1. Hy-Vee (Marion Road) in SF: DEA106
2. Walmart in Vermillion: Complaint
3. Hy-Vee (Sycamore) Forged Prescription
4. Flandreau Santee Sioux Tribe Clinic Pharmacy: DEA 106
5. Shopko Pharmacy in Sisseton: DEA 106
6. Sanford USD Medical Center: DEA 106

E. SD Pharmacists Association Update – Amanda Bacon, Executive Director

SDPhA Executive Director Amanda Bacon submitted the Activity and Financial written reports in the packet and briefly reviewed the following topics:

1. Newly elected Association Officers
2. 2017 Convention award winners
3. List of activities/events pharmacists might offer to celebrate American Pharmacists Month in October.
4. National legislative efforts
5. SDPhA Rebranding – website and social media
6. Pharmacy Technician University (PTU) – new contract with entity; Association serves as PTU program administrator (sets up logins and enrolls users); 12 individuals per group, cost to technician \$325.00. Fills a need for individuals who are not geographically near a State sponsored certification program.

F. Other Reports

1. SDSU College of Pharmacy – Dr. Jane Mort, Pharm D, Acting Dean

College of Pharmacy and Allied Health Professions Department Board Executive Director Shanard-Koenders reviewed the written report provided.

2. SD Health Professionals Assistance Program – Amanda McKnelly, MS, LAC

- No cost increases in 2018
- HPAP has implemented a survey of participants who successfully complete their program.
- The Board of Medicine did not renew their HPAP contract opting instead to launch an "internal monitoring" program.
- HPAP currently serves 135 participants throughout the state and recently added a new staff member to cover West River and Central South Dakota.
- Individuals now have immediate access to HPAP services; there is no longer a wait list.
- Provided HPAP utilization statistics for SD Board of Pharmacy participants and total participants.

3. SD Society of Health System Pharmacists – Jessica Harris, Pharm D, BCPS

- Live CE
- Dakota Night – total attendance 25,000

4. SD Association of Pharmacy Technicians – Jerrie Vedvei, CPhT - Invited

G. Old Business

1. USP <797> proposed revisions – Update – Gary

Briefly reviewed handout content noting:

- September/October, 2018 was the second public comment period for USP <797>.
- Want to avoid a third public comment period as new committee members will have been installed.
- Official rollout of both USP <797> and USP <800> is slated for December 1, 2019.
- Two sections of the Chapter documents (Segregated Compounding Area – SCA and Low Volume Hazardous Drug Compounding) conflict (question no.6 in handout). In this circumstance, the NABP has indicated they will defer to the Board's position on topic.

2. USP <800> and NIOSH 2016 – Paula

- USP <800> official date extended to 12/01/2019 to coincide with USP <797>.
- Pharmacies should not wait for the final document to begin implementation. Pharmacies should review current NIOSH 2016 hazardous drugs list; compile list of hazardous drugs the pharmacy receives, handles, stores, dispenses; perform an Assessment of Risk for hazardous drugs; use proper personal protective equipment, develop policies and procedures for hazardous drug (receiving to dispensing). USP 800 requires a four-step disinfecting process. Each hazardous drug may have a specific cleaning protocol to achieve tray decontamination/deactivation.
- Attended the NABP/FDA Interactive Compliance and Legal Forum held November, 2017. Day 1 topics included Federal requirements for compounding drugs, how the FDA conducts inspections of 503A and 503B facilities and current Good Manufacturing Practices (cGMP). Day 2 focused on outsourcing facility inspections, identifying insanitary conditions and key (cGMP) violations. Day 3 State Panel discussions on USP <797> and <800> inspecting up to standards

3. Office Software

- Continue to review Requests for Proposal (RFP)
- All vendors have similar project implementation timelines (seven to nine months) extending the proposed start date in Fall 2018

4. Hy-Vee Technician Product Verification (TPV) fka Tech-Check-Tech Program

The following was reported by Justin Manning as part of the quarterly update for Sioux Falls Store #4.

- Staff trained - 2 Technician and 1 Pharmacy intern. New full-time technician started in September, continues to train, and has performed no product verification
- Scripts verified by TPV totaled 164 (for September, October, and November).
- Quality verification entered on error to test; error was detected/caught by technician
- TPV is for new and refill prescriptions
- A handout highlighting MTM, immunization, and labor numbers was provided.

Justin Manning requested a new variance, identical to the variance approved by the Board for Hy-Vee Store #4, which allows a certified pharmacy technician/intern to complete final verification of a filled prescription or medication (new and refilled). The new variance would be for Hy-Vee Sioux Falls Store #3 at 3000 S Minnesota Ave and #5 at 3020 E. 10th St and be granted for a length of one year with an option to reapply to

continue the program. Three TPV store locations will provide an opportunity to garner best practices between the sites.

Lisa Rave a motion to approve the variance with a quarterly progress reporting requirement beginning June, 2018. 2nd –Tom Nelson. Motion carried; Diane Dady–aye, Tom Nelson–aye, Lenny Petrik–aye, Lisa Rave–aye, and Dan Somsen–aye.

5. Report on Alchermes/Aristada Pilot Project Minnehaha County Jail – David Bain

Not in attendance

H. New Business

1. InstyMeds Medication Adherence System (IM-MAS), Michael Burns, R.Ph., InstyMeds VP Pharmacy Services
 - An informational presentation / overview of IM-MAS.
 - System is designed to address medication nonadherence as 24-31% of prescription orders written by *Providers* are not filled by patients.
 - Discussed the rationale for utilization in South Dakota hospitals, emergency rooms, urgent care, medical clinics and retail settings; technology can fill the need/gap in rural areas and after hours when pharmacies close.
 - InstyMeds is for first fill acute care only; machine would be located within the provider's facility at a monthly rental cost of \$1,500 - \$1,700.
 - Minnesota has 140 InstyMeds units in hospitals and urgent care sites.
 - South Dakota law allows Prescriber dispensing. South Dakota Board of Pharmacy would license the machine as a pharmacy.

2. Rapid City Regional Asteres Scriptcenter Request – Scott Peterson (not in attendance)
 - Formal request to allow Regional Health Home Plus Pharmacy to place *controlled substance prescriptions* in Asteres Scriptcenter remote pick-up/drop sites for retrieval by patients.
 - The Asteres Scriptcenter is a pick-up site not a dispensing location as all actions of dispensing occur at the pharmacy before the completed prescription is placed in the Scriptcenter.
 - Attendees discussed concerns regarding potential Scriptcenter locales – gas stations, café, etc.... Counter discussion focused on the huge service potential to rural patients and greater security vs. sending controlled substances through the mail.

Dan Somsen made a motion to revise the Board's current policy statement regarding pick-up/drop sites to allow for controlled substance prescription dispensing. 2nd –Lisa Rave. Motion carried; Diane Dady–aye, Tom Nelson–aye, Lenny Petrik–aye, Lisa Rave–aye, and Dan Somsen–aye.

3. Proposed Licensure Compact Bill Discussion
 - In an effort to remove barriers so individuals who move the state can get to work quicker, Governor Dugaard is proposing a licensure compact for all license types in the State of South Dakota
 - Proposal would grant individuals an 18 month temporary license to practice
 - No profession is allowed to opt-out of the compact
 - The idea of a Licensure Compact that includes Pharmacists elicited great concern from attendees whose professional focus is patient safety.
4. Update of Prescribing Authority Document
 - Executive Director Shanard-Koenders briefly reviewed the Prescribers and Prescribing Authority document included in the Board Meeting packet. Document is also posted on the Board website.

5. Pharmacy Technician University and SDPhA – Amanda Bacon

- See Section E of Board Meeting Minutes
6. Proposed Biosimilar Legislation Discussion – Scott Setzepfandt, R. Ph., Genentech Company
- Review of biosimilar legislation being crafted for proposal and consideration during the 93rd legislative session.
 - Biosimilars are a new area not currently taught in pharmacy curriculum. They are biologic substitutions, are a different product and not identical to the original biologic.
 - The proposed legislation has been vetted by all interested parties and has passed in 39 states including Minnesota and Iowa.
 - The terms biologics and interchangeable biologics need to be defined in law.
 - Proposed legislation allows pharmacists to substitute biosimilar interchangeable injectable automatically without getting prescriber permission before substitution. Pharmacist meets the communication requirement threshold when they fill it and bill it.
 - Mr. Setzepfandt is asking pharmacists to provide feedback to the Department of Health regarding the proposed legislation.

J. Other Business Future Board Meeting Dates

1. Recent Meeting News
 - i. 2017 FDA Intergovernmental Meeting on Compounding – September 25-27, 2017
 - Executive Director Shanard-Koenders briefly reviewed handout “What are information sharing /20.88 agreements”
 - FDA would like Boards of Pharmacy to provide a list of compounding pharmacies in their state; Advantage – if a critical / adverse event occurs, Board would have access to FDA’s information; Disadvantage – Board would have to provide any/all information requested by the DEA.
 - ii. DEA Pharmacist Diversion Awareness Conference – October 1, 2017
 - iii. NABP Interactive Executive Officer Forum – October 3-4, 2017
 - iv. National Assn of State Controlled Substance Authorities – October 16-20, 2017
 - v. Critical Point Boot Camp, October 24-27, 2017
 - vi. NABP/FDA Interactive Compliance and Legal Officer Forum – November 28-30, 2017
2. Future Board Meeting Dates
 - i. March 22, 2018 - Sioux Falls, in conjunction with SDSHP, Location TBD
 - ii. June 8, 2018 – Sioux Falls, Location TBD
 - iii. September 20, 2018, Sioux Falls, in conjunction with SDPHA, Location TBD
 - iv. December 7th or 14th, 2018???? Location TBD
3. Future Meetings
 - i. DEA Annual Diversion Conference, December 12-13, 2017, Dallas, TX
 - ii. SDSHP 2018 Annual Meeting, March 23-24, 2018, Sioux Falls, BW Ramkota
 - iii. NABP Annual Meeting, May 5-8, 2018, Hyatt Regency Denver

K. Executive Session: per SDCL 1-25-2; legal issues

- Tom Nelson motioned to move to go into Executive Session
- The Board members came out of Executive Session and went back into Regular Session

L. Adjourn

Adjourn at 1:10 PM MST – Motion to adjourn made by Board Member Lisa Rave, seconded by Board Member Lenny Petrik. Motion passed; Diane Dady–aye, Tom Nelson–aye, Lenny Petrik-aye, Lisa Rave-aye, and Dan Somsen–aye. Meeting adjourned.